

# Notice of Allowability

Application No.

09/392,822

Examiner

Joseph T. Woitach

Applicant(s)

YU ET AL.

Art Unit

1632

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to June 9, 2004.
2. ☒ The allowed claim(s) is/are 1,8,14-16,21,24-26 and 32-38, 40-54.
3. ☒ The drawings filed on 9/9/1999 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

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### **DETAILED ACTION**

This application filed September 9, 2000, claims benefit to provision application filed September 10, 1999.

Applicants' amendment filed June 9, 2004, has been received and entered. The specification has been amended. Claims 1 and 35 have been amended. Claims 47-54 have been added. Claims 1, 8, 14-16, 21, 24-26 and 32-54 are pending .

### ***Election/Restriction***

It was indicated that claims 47-54 are directed to an invention that is independent or distinct from the invention the claims set forth a vector that is different and distinct from that previously claimed and examined. The claims set forth a vector requiring two responsive elements controlling the expression two different transgenes. However, upon review of the claims, while the vectors are structurally different at the specific sequence level and can be functionally different dependent on the properties of a varying number and use of different promoters, the examined claims do encompass such vectors. The examined claims encompass and would make obvious the claims previously examined. Therefore, the restriction requirement is withdrawn.

### ***Examiner's Amendment***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

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1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Pamela J. Sherwood on August 31, 2004.

The application has been amended as follows:

In claim 35, in the second line, after "target cell" insert --with a disrupted RB function--; in line six, delete [[target cell exhibits disrupted RB function and said]]; and in line seven, delete [[said target cell]] and insert therein --a target cell with a disrupted RB function--.

Cancel claim 39.

In claim 47, line seven, after "E1B and E4" delete [[; and in a target cell wherein said hypoxia inducible factor-1 is present]] and insert therein --wherein--; and in the final line, after "selective replication" insert --in a target cell in which a hypoxia inducible factor-1 is present--.

In claim 50, line seven, after "E1B and E4" delete [[; and in a target cell wherein RB function is disrupted, ]] and insert therein --wherein--; and in the final line, after "selective replication" insert --in a target cell in which RB function is disrupted--.

In claim 53, line four, after "hypoxia inducible factor-1" delete [[; and in a tumor, ]] and insert therein --wherein--; and in the final line, after "selective replication" insert --in a tumor cell in which a hypoxia inducible factor-1 is present--.

In claim 54, in the first line, after "cytolysis of a" insert --tumor--; in line seven, after "E1B and E4" delete [[; and in a tumor target cell, ]] and insert therein --wherein--; and in the final line, after "selective replication" insert --in a tumor target cell in which E2F-1 is present--.

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***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance:

The amendments to the claims has obviated the specific basis of each of the rejections made under second paragraph of 35 U.S.C. 112. With respect to the rejection made under 35 U.S.C. 103(a) citing Henderson *et al.* (WO 97/01358) Hallenbeck *et al.* (WO 96/17053), Walther *et al.* (Mol. Biotechnol., 6:267-286), Dachs *et al.* (Nat. Med., 3(5):515-520,), Dachs *et al.* (Oncol. Res., 9:313-325), Advani *et al.* (Semin. Oncol., 24(6):633-638), and Parr *et al.* (Nat. Med., 3(10):1145-1149), Applicants have noted the contribution of each of the cited references however have argued that the difference between the cited art and the present invention is the use of hypoxia responsive elements that relate to the status of the cell rather than the type of cell as taught in Henderson *et al.* and Hallenbeck *et al.* Vectors similar to the present instantly claimed have also been disclosed in 5,834,306 and 2003/0095989, however these vectors are used to express other transgenes not adenoviral genes essential for replication. In addition, Applicants have provide three post-filing references (Cuevas *et al.* Cancer Res 63:6877-6884, Hernandez-Alcoceba *et al.* Human Gene Therapy 13:1737-1750, and Li *et al.* abstract 445 from ASGT 7<sup>th</sup> Annual Meeting) reducing to practice and demonstrating the effectiveness of the instantly claimed products and methods.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

A handwritten signature in cursive script that reads "Joe Woitach".

JOSEPH WOITACH  
PATENT EXAMINER